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Attorney Docket No. VPI/98-18 DIV US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: David Lauffer and Michael Mullican
ASSIGNEE: Vertex Pharmaceuticals Incorporated
DIVISIONAL OF: 10/039,886 EXAMINER: Charanjit Aulakh
FILING DATE: Herewith ART UNIT: 1625
FOR: BICYCLIC DERIVATIVES

August 1, 2003
Cambridge, Massachusetts 02139-4242

MS Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, Applicants hereby make of record the documents listed below and on the attached modified Form PTO-1449 (submitted in duplicate) in the above-identified application, copies of which are submitted herewith. This Information Disclosure Statement is being filed:

- ☐ within three months of the filing date of the National Application;
- ☐ within three months of the filing date of the entry of the National Stage, as set forth in 37 C.F.R. §1.491, in an International Application; or
- ☒ before the mailing date of a first Office Action on the merits in the above-identified case.

Accordingly, no fee or certification is required. 37 C.F.R. §1.97.

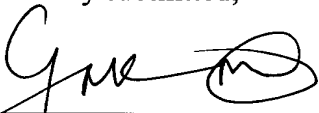
A copy of each of the above-identified information is enclosed unless otherwise indicated on the attached Form PTO-1449 (modified). It is respectfully requested that the Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims, and signs the enclosed form PTO-1449 to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application.

APPLICANTS: Lauffer et al.
U.S.S.N.: Not Yet Assigned

By submitting this Information Disclosure Statement, the Applicant makes no representation that: (1) a search has been performed, of the extent of any search performed, or that more relevant information does not exist; (2) the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b); and (3) the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his/her own conclusion regarding the relevance of the cited information. An early and favorable action is hereby requested. Please charge any additional fees that may be due, or credit any overpayment of same, to Deposit Account No. 50-0725, Reference No. VPI/98-18 DIV US.

Respectfully submitted,



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| Modified Form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) | Application Number | Not Yet Assigned |
| | Filing Date | Herewith |
| | First Named Inventor | David Lauffer |
| | Group Art Unit | 1625 |
| | Examiner Name | C. Aulakh |
| | Attorney Docket Number | VPI-98-18 DIV US |

| U.S. PATENT DOCUMENTS | | | | | | | |
|-----------------------|----------|--------------------------|------------|-------------------------------------|-------|-----------|----------------------------|
| Exam Initials | Cite No. | U.S. Patent Document No. | Issue Date | Name of Patentee(s) or Applicant(s) | Class | Sub Class | Filing Date If Appropriate |
| | A1* | 5,773,458 | 30-Jun-98 | Sabb, et al. | | | 17-Oct-1997 |
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| FOREIGN PATENT DOCUMENTS | | | | | | | |
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| Exam Initials | Cite No. | Foreign Patent Document Office Number | | Name of Patentee(s) or Applicant(s) | Date of Publication | Translation Yes No | |
| | B1* | | WO 95/03302 | SmithKline Beecham PLC | 02-Feb-1995 | | |
| | B2* | | 0 398 629 A2 | Merck Sharp & Dohme Ltd. | 22-Nov-1990 | | |
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| OTHER NON PATENT LITERATURE DOCUMENTS | | |
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| Exam Initials | Cite No. | Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc. |
| | C1* | Bulacinski, A.B., et al., "Synthesis of Acyclic and Heterocyclic Derivatives of 2-Carboxyquinuclidine. VII.", Acta Polonia Pharmaceutica, Drug Research, 51(6):489-492 (1994). |
| | C2* | Biniecki, S., et al., "Synthesis of (R), (S)-Phenylalkylamides of Quinuclidine-2-carboxylic Acid and Their Reduction to Amines.", p. 740, column 1, XP002150143 abstract & ACTA Polonia Pharmaceutica, 38(3):293-296 (1981). |
| | C3* | Binecki, S., et al., "Synthesis of R, S-Phenylalkylamides of Quinuclidine-3-carboxylic Acids and their Reduction to Amines", p. 56, column 2, XP002150144 abstract & ACTA Polonia Pharmaceutica, 38(6):641-645 (1981). |
| | C4* | Bulackinski, A., et al., "Synthesis of Acyclic and Heterocyclic Derivatives of 2-Carboxyquinuclidine.", p. 614, column 2, XP002150145 abstract & ACTA Polonia Pharmaceutica, 46(5):435-439 (1989). |
| | | |

* a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, U.S.S.N. 10/039,886, filed January 3, 2002, and relied upon for an earlier filing date under 35 U.S.C. §120 (continuation, continuation-in-part, and divisional applications).

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| Examiner Signature | | Date Considered | |
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered.

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| | Filing Date | Herewith |
| | First Named Inventor | David Lauffer |
| | Group Art Unit | 1625 |
| | Examiner Name | C. Aulakh |
| | Attorney Docket Number | VPI-98-18 DIV US |

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| | A1* | 5,773,458 | 30-Jun-98 | Sabb, et al. | | | 17-Oct-1997 |
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| Exam Initials | Cite No. | Foreign Patent Document Office Number | Name of Patentee(s) or Applicant(s) | Date of Publication | Translation Yes No |
| | B1* | WO 95/03302 | SmithKline Beecham PLC | 02-Feb-1995 | |
| | B2* | 0 398 629 A2 | Merck Sharp & Dohme Ltd. | 22-Nov-1990 | |
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| OTHER NON PATENT LITERATURE DOCUMENTS | | |
|---------------------------------------|-------------|--|
| Exam Initials | Cite No. | Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc. |
| | C1* | Bulacinski, A.B., et al., "Synthesis of Acyclic and Heterocyclic Derivatives of 2-Carboxyquinuclidine. VII.", Acta Polonia Pharmaceutica, Drug Research, 51(6):489-492 (1994). |
| | C2* | Biniecki, S., et al., "Synthesis of (R), (S)-Phenylalkylamides of Quinuclidine-2-carboxylic Acid and Their Reduction to Amines.", p. 740, column 1, XP002150143 abstract & ACTA Polonia Pharmaceutica, 38(3):293-296 (1981). |
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